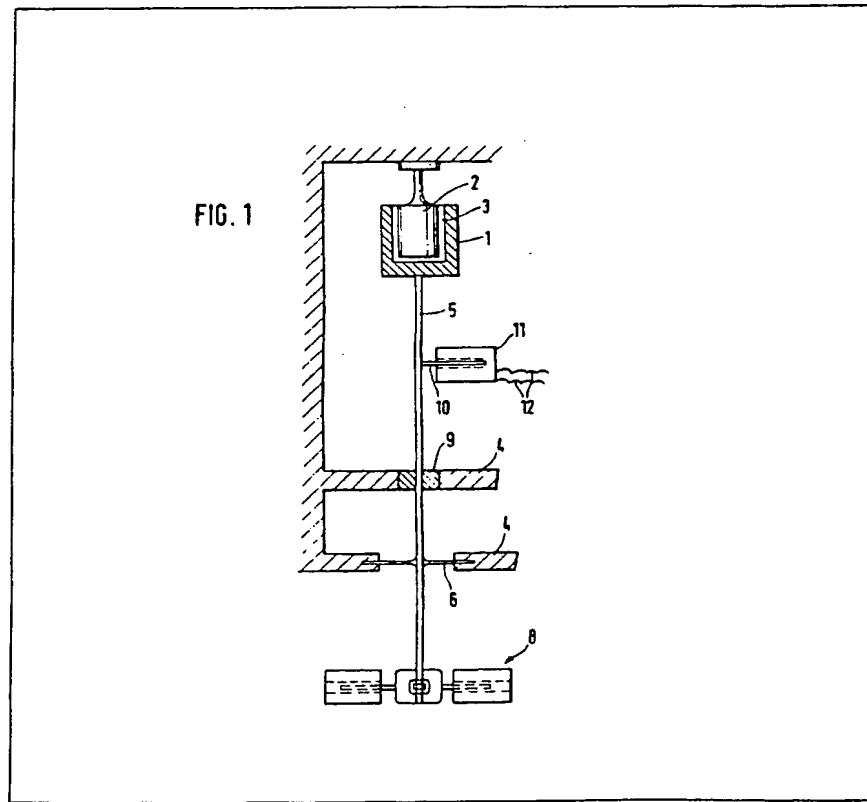


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(54) Apparatus for and a method of measuring changes of state in coagulating fluids

(57) An improved apparatus and method for measuring changes of state in coagulating fluids, such as blood, wherein the fluid is located in a gap 3 between a test member (2) Figure 1 and a beaker (1), which is arranged at the top of a rod (5) at the bottom end of which are coils (8) for forming a rotating electromagnetic field, cores entering the coils being secured radially to the rod, which is clamped in a resilient diaphragm (6), means (10, 11, 12) being provided for recording the movement of the rod due to the field. This movement unexpectedly exhibits distinct maxima related to the changes of state and enables, for example, a distinction to be made between normal and pathological blood coagula.



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FIG. 1

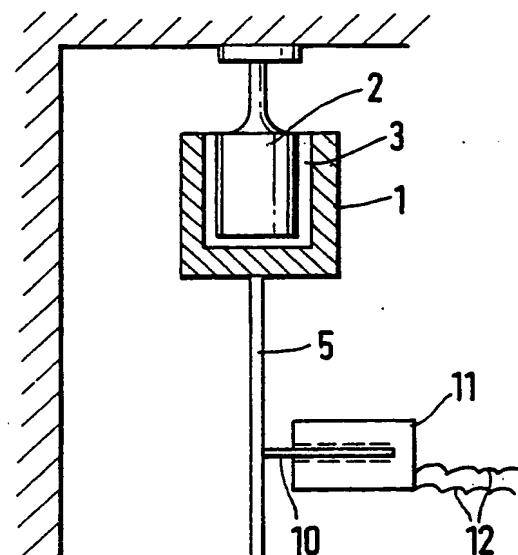
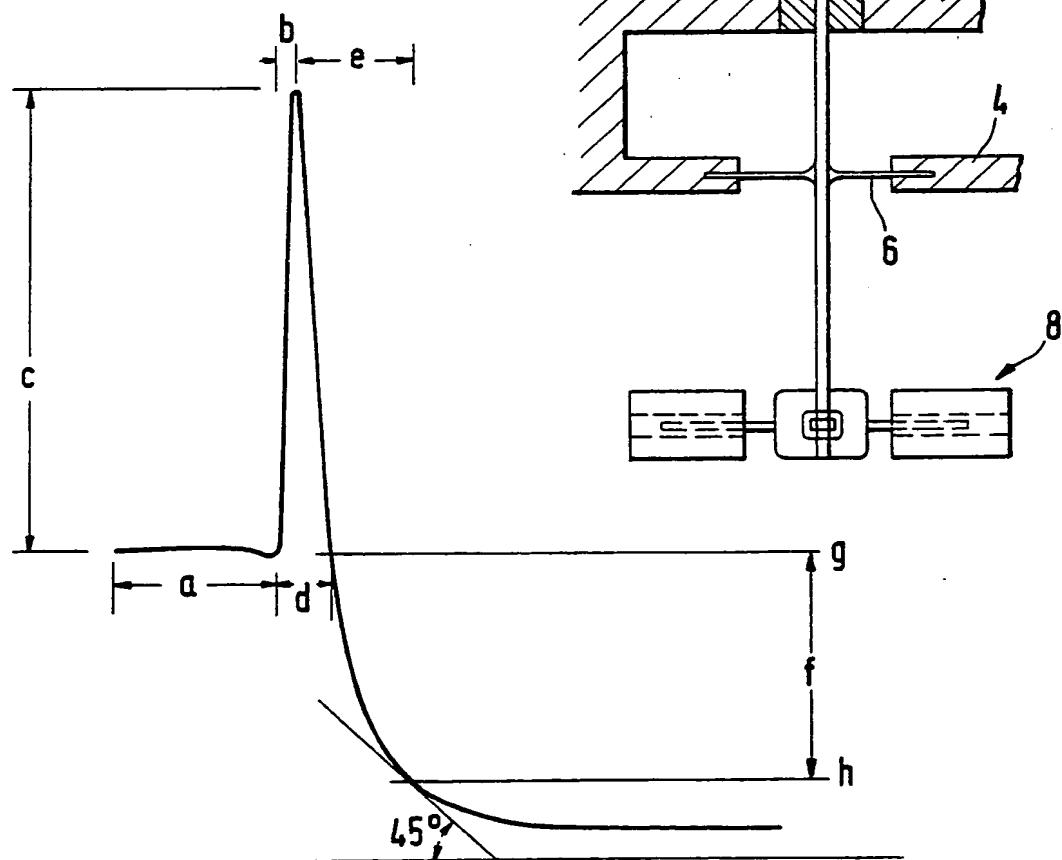


FIG. 2



SPECIFICATION

Apparatus for and a method of measuring changes of state in coagulating fluids

5 This invention relates to apparatus for and a method of measuring changes of state in coagulating fluids.

10 German Offenlegungsschrift No. 2,019,341, originating from the same inventor, describes an apparatus for performing continuous measurements of coagulating liquids, preferably blood and derivatives thereof, which apparatus is provided with means for producing shearing and deformation effects in the coagulating fluid, which means are in the form of a circularly cylindrical beaker and a test member which is also of circularly cylindrical configuration which is suspended from a torsion wire and which is located in the beaker, an annular 15 gap for receiving the fluid being formed between the beaker and the test member. An orbital motion is imparted by appropriate means to the wall surfaces of the beaker which confine the fluid.

20 This apparatus is designed and adjusted such that the peripheral speed of the orbital movement substantially approximates to the rate of flow of the blood in human blood vessels. In this apparatus, it has already been proposed, inter alia, to produce the orbital movement by a rotating electrical field 25 which correspondingly acts upon the beaker.

Thus, this apparatus permits measurement of the coagulation of the blood by subjecting the fibrin, produced during coagulation, to a specific shearing stress. By appropriate metering of this shearing stress, the resilient resistance of the coagulum can be increased far more rapidly compared with an apparatus in which the fluid is not subjected to a metered shearing stress of this kind during coagulation, that is, during the formation of the coagulum. 35 Thus, it is far simpler to distinguish between normal and pathological blood coagula than with the original apparatus described in German Patent No. 845,720 of the same inventor. This renders it possible substantially to improve the diagnostic routine. 40 At the same time, it is possible sharply to define the so-called coagulation time which elapses until the coagulum commences to form and which is normally difficult to define.

Based on the fundamental ideas set forth above, 50 and in accordance with the invention, an improved apparatus is proposed as well as a preferred measuring method to be performed by this improved apparatus.

The improved apparatus is distinguished essentially in that the beaker for receiving the fluid is arranged at the top end of a perpendicular resilient rod at the bottom end of which is arranged a plurality of coils for forming a rotating electromagnetic field, cores entering the coils being secured radially 55 to the rod. The resultant movement of the entire arrangement, produced by the various components of the measuring apparatus and the fluid to be measured, is picked up by a further, laterally disposed coil whose core is also arranged radially on 60 the rod. The rod is clamped in a resilient diaphragm 65

which extends radially thereof and which serves to hold the entire arrangement.

Furthermore, a vibration-damping element acting upon the rod may be provided.

70 In the first instance, the same measurements with the evaluation of the same changes in the fluid to be measured can be performed by this arrangement as are performed by the known apparatus described initially. However, in addition to this, the present 75 arrangement can be adjusted in a simple manner to a specific natural oscillation frequency, this being of importance in connection with the method to be performed by the present apparatus.

With this method, the measured values are ascertained in the resonance range of the natural oscillation of the measuring arrangement. Unexpectedly, it has transpired that, with a method of this type, the values coming from the pick-up coil and which can be recorded by, for example, a curve tracer, exhibit 80 distinct maxima in dependence upon the states of change which are of interest in the fluid to be measured.

Furthermore, it was found that the most favourable natural frequency of the arrangement is 90 approximately 35 Hz, and usable measurement results can also still be obtained at approximately twice the frequency and half the frequency, only, of course, taking into account certain variations in wave length and wave amplitude which are dependent upon one another, i.e. the frequency and the amplitude.

Thus, the formation of the resilient fibrin coagulum can be detected even more sensitively by the new apparatus in that the resilient resistance of 100 the fibrin coagulum, increasing during coagulation, leads to the change of the natural frequency of the resiliently suspended measuring sensor, that is, the rod. This rod can be regarded as an orbitally oscillating pendulum. This change of the natural frequency leads to a shift relative to the forced drive 105 frequency. According to the chosen starting position, there is a phase shift between the measuring sensor and the drive and also a change in amplitude in strict dependence, hitherto not attained, upon the 110 quality and the quantity of the formation of the resilient material, such as the fibrin coagulum in the blood, which are thus rendered measurable.

The shearing stress exerted in a physiologically limited range on the coagulum produced multiplies 115 the resilient strength of the fibrin network if the mechanical load resulting from the shearing stress acts during the production of the fibrin network. In other words, the fibrin network would be substantially more open if it were not built up under shearing load. Furthermore, the resonance shift caused by the object to be measured, that is the fibrin coagulum, is rendered usable for the measurement. Both these factors lead to a considerable increase in, and thus easier recognition of, the differences 20 between normal and pathological coagulation processes.

An embodiment of the measuring apparatus is shown purely diagrammatically and by way of example in the accompanying drawings, as well as 130 a measurement curve.

Figure 1 shows the parts which are important and critical to the action of the apparatus. A cylindrical member 2 is inserted in a known manner into a beaker 1 which is at the same time the actual testing member. The fluid, whose coagulation processes are to be measured, is introduced into the annular gap 3 formed between the two said parts. The cylindrical member 2 is rigidly connected to the frame 4 of the apparatus. The beaker 1 is arranged at the top end of a rod 5 which is made from rigid material and which is mounted in the frame 4 of the apparatus by means of a circular resilient diaphragm 6. A coil arrangement 8 at the lower end of the rod 5 produces a rotating electro-magnetic field 15 and imparts to the rod 5 an orbital movement which differs in a specific manner from the natural frequency of the rod 5 and which is of, for example, somewhat higher frequency. The circular oscillation can be damped by means of a damping device 9. The damping device can comprise, for example, an annular member of resilient or non-resilient material which is mounted in the frame 4 and which embraces the rod 5.

The essential motion produced in the rod 5 by the coil arrangement 8 is an angular oscillation about its axis. Thus when the rotating electromagnetic field passes the cores attached to the lower end of the rod, these are deflected until brought to rest by a restoring force exerted by the resilient diaphragm 30 6. The field, however, continues to rotate allowing the cores to move back under the restoring force of the diaphragm. Eventually the field passes the cores again and deflects them once more in the initial direction.

35 A further core 10, which enters a pick-up coil 11, is arranged on the rod 5 and is connected by way of leads 12 to any optional indicating element such as a curve tracer.

The curve which is shown in Figure 2 and which is plotted by, for example, a curve tracer of this type, clearly shows the maximum indicating the state of change. It is caused by the fact that the resilient fibrin produced in the annular gap increases the natural frequency of the orbital movement of the rod and thus shifts the orbital movement of the rod into the range of the forced frequency. The resonance occurring thereby causes the increase in amplitude, i.e. the maximum of the curve. This is exceeded and leads to the reversal of the curve as soon as the resilient moment of the coagulum increases the natural frequency of the apparatus beyond the forced frequency. Thus, very slight changes in the state of the coagulum produced, in which, for example, the blood-platelets are also 45 involved, are manifest in a pronounced manner by the characteristic and shape of the measured curve.

The measurement curve ("resonance thrombograph") shows the following features which are given as measured variables in minutes and seconds in the horizontal and in mm in the perpendicular:

- a) = coagulation time
- b) = curve rise time
- c) = maximum amplitude

d) = short curve descent time

e) = long curve descent time

f) = negative amplitude

g) = base line (starting deflection)

70 h) = zero line (zero amplitude)

Measurement of the values of a, c and d or e is sufficient for the routine assessment of the measurement curve.

75 CLAIMS

1. Apparatus for performing continuous measurements of coagulating fluids, which apparatus has means for producing shearing and deformation

80 effects in the coagulating fluid, which means are in the form of a circularly cylindrical beaker and a testing member which is also of circularly cylindrical configuration and which is attached to a frame of the apparatus and which is located in the beaker, an annular gap for receiving the fluid being formed between the beaker and the test member, wherein the beaker for receiving the fluid is arranged at the upper end of a perpendicular rod which is held and clamped in a resilient diaphragm extending radially 90 of the rod, there being arranged at the lower free end of the rod a plurality of coils which form a rotating electro-magnetic field, cores entering the coils being secured radially to the rod, and a further radially arranged core being provided on the rod for 95 the purpose of picking up the resultant movement of the said rod, which further core enters a pick-up coil connected to an indicating device.

2. Apparatus as claimed in claim 1, in which there is provided an oscillation-damping element 100 which acts upon the rod.

3. A method of ascertaining, by means of an apparatus as claimed in claim 1, measured values given by the changes of state in coagulating fluids, wherein the measured values are ascertained 105 around the resonance range of the natural oscillation of the measuring arrangement provided by the rod and the parts provided thereon.

4. A method as claimed in claim 3, wherein the natural frequency of the measuring range is approximately 35 Hz.

5. A method as claimed in claim 3 or 4, wherein the measured values are ascertained by way of the degree of shift between drive pulse and direction of deflection.

115 6. A method as claimed in claim 5 in which the values are ascertained electronically.

7. A method as claimed in any one of claims 3 to 6 in which the coagulating fluid is blood or a derivative thereof.

120 8. An apparatus as claimed in claim 1 and substantially as hereinbefore described with reference to and as illustrated in Figure 1 of the drawings.